§440.171 Penicillin V oral dosage forms.

§440.171a Penicillin V capsules.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Penicillin V capsules are composed of penicillin V with one or more suitable and harmless lubricants. Each capsule contains either 125 milligrams (200,000 units) or 250 milligrams (400,000 units) of penicillin V. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams or units of penicillin V that it is represented to contain. Its moisture content is not more than 2 percent. The penicillin V used conforms to the standards prescribed by §440.71(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of §432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of §431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The penicillin V used in making the batch for potency, moisture, pH, penicillin V content, and crystallinity.

(*b*) The batch for potency and moisture.

(ii) Samples required:

(*a*) The penicillin V used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of 30 capsules.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Sample preparation.* Place a representative number of capsules into a high-speed glass blender jar containing sufficient absolute methyl alcohol to give a solution of convenient concentration. Blend for 3 to 5 minutes.

(ii) *Assay procedures.* Use either of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(a) Microbiological agar diffusion assay. Proceed as directed in §436.105 of this chapter. Immediately dilute an aliquot of the methyl alcohol solution with 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to the reference concentration of 1.0 unit of penicillin V per milliliter (estimated).

(b) Iodometric assay. Proceed as directed in §436.204 of this chapter, diluting an aliquot of the methyl alcohol with solution 1 to the prescribed concentration.

(2) *Moisture.* Proceed as directed in §436.201 of this chapter.

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§440.171b Penicillin V for oral suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Penicillin V for oral suspension is composed of penicillin V with or without one or more suitable and harmless suspending agents, colorings, flavorings, and buffer substances. When reconstituted as directed in the labeling, each millilter contains 25 milligrams (40,000 units), 50 milligrams (80,000 units) or 208.3 milligrams (333,333 units) of penicillin V. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams or units of penicillin V that it is represented to contain. Its moisture content is not more than 1 percent. When reconstituted as directed in the labeling, its pH is not less than 2.0 and not more than 4.0. The penicillin V used conforms to the standards prescribed by §440.71(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of §432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of §431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The penicillin V used in making the batch for potency, moisture, pH, penicillin V content, and crystallinity.

(b) The batch for potency, moisture, and pH.

(ii) Samples required:

(a) The penicillin V used in making the batch: 10 packages, each containing approximately 300 milligrams.

(b) The batch: A minimum of 6 immediate containers.

(b) *Tests and methods of assay*—(1) *Potency.* Use either of the following methods; however, the results obtained from the iodometric assay shall be conclusive.